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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,092	12/31/2003	Zhandong Don Zhong	034827-0112	1890
30542	7590	08/25/2006	EXAMINER	
FOLEY & LARDNER LLP			BAUGHMAN, MOLLY E	
P.O. BOX 80278			ART UNIT	PAPER NUMBER
SAN DIEGO, CA 92138-0278			1637	

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/750,092

Applicant(s)

ZHONG ET AL.

Examiner

Molly E. Baughman

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 7/6/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 1-27 and 33-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 28-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: Stratagene 1988 Catalog, pg.39

### **DETAILED ACTION**

1. Applicant's election without traverse of Group III, claims 28-32, drawn to a kit in the reply filed on 7/6/06 is acknowledged.
2. Claims 1-27 and 33-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/6/06.

### ***Objections/Informalities***

3. The use of the trademarks "CaptAvidin" and "Captivate" have been noted in this application. The entire word should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1637

Claims 28-30 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Imagawa et al (US 4,942,122).

Imagawa et al. teach a kit in Claims 4-8 comprising a primed RNA template, and a nucleotide triphosphate that is tritiated dTTP, wherein the DNA synthesized will be in the form of poly rA: poly dT which will not filter through on a microporous filter, providing a means to capture the synthesized DNA molecule for detection of reverse transcriptase activity. The kit further comprises an enzyme reaction buffer, which includes 5 mM of magnesium chloride.

5. Claims 28-30 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Eberie et al (US 5,413,906).

Eberie et al. teach a kit containing a template nucleic acid, at least one detectable and immobilizable mononucleoside triphosphate, and preferably a primer (column 8, lines 23-65). The kit also contains reagents for detection, such as pH-buffer, detergent, complex former, co-factors, salts and anti-oxidizing agents (column 8, lines 37-57). Specific examples describe an RT-buffer comprising 5mM of  $MgCl_2$  (Column 14, lines 47-49). The mononucleoside triphosphates are triphosphates of nucleosides which can contain natural bases such as adenine, guanine, cytosine, and uracil or thymine (column 3, lines 34-49), which can be detectable through a dye, a fluorescent label or a component of an immunologic reaction such as an antigen, antibody or hapten. The nucleosides can also be immobilizable through binding

Art Unit: 1637

partners such as biotin-avidin, biotin-streptavidin, antigen-antibody, hapten-antibody, etc (column 4, lines 1-20).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Furfine et al. (WO 01/38587 A2), in view of Stratagene (1988 Catalog).

Furfine et al. disclose a method of detecting polynucleic acid polymerase activity by providing primer-template complex and a nucleotide labeled with an energy-emitting chemical species (claim 1). The nucleotide is selected from the group consisting of

Art Unit: 1637

dUTP, dTTP, dATP, dCTP, dGTP, ATP, CTP, UTP, GTP (claim 2), wherein the energy-emitting chemical species (i.e. label) is a thermotropic acridinium ester and acridinium salt (claim group 11,5,4,1). According to the specification, such labels can also be biotinyl moieties that can be detected by avidin (e.g. streptavidin containing a fluorescent marker) which are incorporated into the polynucleic acid primer-template complex via a labeled nucleotide (page 8, lines 4-12). The method further comprises a reverse transcriptase polymerase (see claim 14) and numerous examples in the specification use various assay buffers for a reverse transcriptase reaction (i.e. example 1 and 3). Such examples disclose the use of various concentrations of  $MgCl_2$  ranging from 1 mM to 13.3 mM, wherein the inventors state the examples "are intended to be exemplary only and that numerous changes, modifications and alterations can be employed without departing from the spirit and scope of the invention" (page 14, lines 13-16).

Furfine et al. do not disclose the use of kits.

One of ordinary skill in the art would have been motivated to package the components of the method of Furfine et al. into a kit because it was conventional in the art to package together reagents into a kit for the convenience of practicing methods, as explained by Stratagene in their 1988 Catalog. Stratagene states on page 39:

*"Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus, one need not purchase gram quantities of 10 different reagents, each of which is needed only in microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and*

Art Unit: 1637

*freezers, one quickly realizes that it is actually more expensive for a small number of users to prepare most buffer solutions from basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control..."*

As such, the skilled artisan would have had a reasonable expectation of success in packaging the materials in the method of Furfine et al. into a kit as suggested by Stratagene. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make a kit and include the claimed materials therein.

7. No claims are free of the prior art.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Molly E. Baughman whose telephone number is 571-272-4434. The examiner can normally be reached on Monday-Friday 8-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Molly E Baughman  
Examiner  
Art Unit 1637

*meb 8/18/06*

*Kent R. Horlick*  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

*8/21/06*